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WYETH PATENT LAW GROUP 5 GIRALDA FARMS MADISON, NJ 07940			PORTNER, VIRGINIA ALLEN	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/840,485

Applicant(s)

BIGBIE ET AL.

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,9 and 15-22 is/are rejected.
- 7) ☒ Claim(s) 3,9 and 15-22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 3,9,15-22 and additional embodiments recited in the other pending claims under consideration.

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### **DETAILED ACTION**

Claims 1-22 are pending; claims 3,9,15-22 stand withdrawn from consideration.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Election/Restrictions***

2. Newly submitted claims 1-22 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: All of the claims have been amended to recite the phrase:

a. “plasmid DNA obtained from a horse diagnosed to have equine protozoal myoencephalitis that is derived from *Sarcocystis neurona* or *Neospora hughesi* or a mixture thereof”; and

b. “a tachyzoite antibody-inducing antigen derived from said *Neospora hughesi* cells” which are inventions that is structurally and functionally distinct from *Sarcocystis neurona* whole cell antigen immunogens and protein antigens derived therefrom.

c. Combination compositions of *S. neurona* and *Neospora hughesi* cells (previously withdrawn from consideration)

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 3, 9, 15-22 remain withdrawn and newly submitted amended combination claim limitations set forth in claims 3,9,15-22 which recite inventions directed to tachyzoite antigens of *Neospora hughesi*, as well as plasmid DNA from either *Sarcocystis neurona* or *Neospora hughesi*, and mixtures thereof, are

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withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Objections/Rejections Withdrawn***

1. **Deposit Requirements met** :The amendment filed After Final, on May 12, 2005 objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure, has been obviated through submission of a Declaration of Deposit/ Deposit Receipt showing that the deposit was made under the Budapest Treaty was submitted and the statement that “all restrictions upon public access to the deposit will be irrevocably removed upon the grant” of a Patent.
2. **Claim Objections**: Claims 1, and 5 objected to because of the informalities has been obviated through amendment of the claims to remove “;” semi-colons, and the phrase “selected from the group consisting of”.
3. Claim 1 rejected under 35 U.S.C. 112, second paragraph for reciting the phrase “a merozoite or tachyzoite antibody inducing antigen derived from said cells” has been obviated by amending the claim to clearly set forth to which cells the phrase “said cells” refers.
4. Claims 4,6 and 7 rejected under 35 U.S.C. 112, second paragraph for reciting the limitation "unit dose form" has been obviated based upon the claim amendment to refer to a dosage form defined in the instant Specification at page 10, lines 20-23.
5. Claim 5 rejected under 35 U.S.C. 112, second paragraph for reciting the phrase “effective immunizing amount” has been amended to define the amount to be a “therapeutically effective amount”.
6. Claim 8 rejected under 35 U.S.C. 112, second paragraph for reciting a combination of claim limitations that functionally defined the “amount” that is present in the composition has been obviated through amendment of the claim to recite the phrase “antibody response which has a neutralizing effect on Sarcocystis neurona merozoites.”
7. Claims 10-14, rejected under 35 U.S.C. 112, second paragraph for reciting the phrase “about 1% to 50% wt/wt” (claim 10), or “about 5% to 20% wt/wt” (claim 11) has been obviated by amending the claims to recite the term “by weight”.

### ***Response to Arguments***

### ***Objections/Rejections Maintained***

8. **(Scope of Enablement)** The rejection of claims 1-2, 4-8 and 10-14 under 35 USC 112, first paragraph (vaccine compositions), while being enabled for the inducing of S.neurona specific neutralizing antibodies with inactivated merozoite whole cells, does not enable the use of any derived antigen, to include single proteins that comprise epitopes (definitions provided on pages 7, 10 (paragraphs 1-2) and 12) of the instant

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Specification) for induction of a protective immune response is traversed on the grounds that “substantive evidence that the antigens of the present invention will be effective for their intended purpose of preventing infections is not required by statute. Working examples of each and every embodiment of an invention to prove absolute success are not necessary. In fact, there is not statutory prohibition against the possibility that the claims might include an inoperative antigenic substance. Routine screening is always permissible. Enablement only requires that the ordinary practitioner can practice the invention without an undue amount of experimentation.

9. It is the position of the examiner that the rejection over the claims was a SCOPE of enablement, not a complete lack of enablement. While Applicant’s statements with respect to the requirements for enablement are true, it is also true that predictability or unpredictability within an art must be considered when determining whether the amount of experimentation required is undue experimentation.

The Wands factors (for elected invention) must be considered:

.the *quantity of experimentation* necessary is undue for the development of protozoan vaccines without a prior showing of protection against infection. The art of vaccines for protozoan pathogens is unpredictable, and each and every antigen would need to be shown to provide protection against infection in light of the fact that even highly immunogenic compositions that were believed to be able to provide protection, have failed in challenge experiments. Gradoni et al (2005) teaches that a multi-subunit recombinant vaccine failed to protect the protozoan host animal from infection and progression of disease. Hagan et al (2003) teaches that developing vaccines against parasitic worms presents many challenges and even vaccine candidate antigens have been found to fail in providing protection against infection (see abstract). Hagen et al teaches that there “are complex questions to be addressed regarding the design, implementation and interpretation of schistosome vaccine trials(p1275,col.2)”. Andrianarivo et al (2000) discloses an adjuvanted killed tachyzoite preparation failed to prevent foetal infection upon challenge (see title). Pye et al (1991, title) describes vaccine failure of a composition that comprised recombinant vaccinia viruses expressing multiple protozoan antigens

.the *amount of direction or guidance* presented: limited to a whole cell inactivated merozoite antigen of ATCC strain PTA-2972

.the presence or absence of working examples: limited to a whole cell inactivated merozoite antigen of ATCC strain PTA-2972 (see plaque reduction Examples) showed partial in vitro protection;

.the nature of the invention: well known, but protozoan vaccines are unpredictable;

.the state of the prior art: still developing (see protozoan references above, especially Hagan et al );

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- .the relative skill of those in the art: high;
- .the predictability or unpredictability of the art: very unpredictable ;
- .breadth of the claims: broad.

Therefore, while working examples are not required, no guidance or teaching is provided in the instant Specification as to which derived antigens to choose from the many possible antigens, and fragments of antigens (protein subunits) that could or would induce a protective immune response against challenge in vivo. The working examples provided do not provide the missing information that would lead one of skill in the art to select protective derived antigens. The scope of enablement is maintained for reasons of record and responses set forth herein.

10. The specification fails to teach how to formulate and use the claimed vaccines. The term "vaccine" encompasses the ability of the specific antigen to induce protective immunity to infection or disease induction. The specification does not provide substantive evidence that the claimed vaccines are capable of inducing protective immunity using any single antigen, or protein for treating infection, or preventing infection by *S. neurona*. This demonstration is required for the skilled artisan to be able to use the claimed vaccines for their intended purpose of preventing infections caused by *S. neurona* protozoan. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines, i.e. would not be able to accurately predict if protective immunity has been induced. The ability to reasonably predict the capacity of a single pathogen immunogen to induce protective immunity from in vitro antibody reactivity studies is problematic. Ellis exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the identification of a protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies"(page 572, second full paragraph). Unfortunately, the art is replete with instances where even well characterized antigens that induce an in vitro neutralizing antibody response fail to elicit in vivo protective immunity. See Boslego et al. wherein a single protein fails to elicit protective immunity even though a high level of serum antibody response is induced (page 212, bottom of column 2). Accordingly, the art indicates that it would require undue experimentation to formulate and use a successful vaccine without the prior demonstration of vaccine efficacy.

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While the Specification teaches inactivated whole cells that are able to induce neutralizing protozoicidal antibodies, the specification fails to provide an adequate written description of other compositions that can be used in the claimed vaccine compositions, the skilled artisan would be required to de novo locate, identify and characterize the claimed other proteins. This would require undue experimentation given the fact that the specification is completely lacking in teachings as to what other surface proteins would function as vaccine antigen with the claimed characteristics.

11. **Objection:** Claims 1-2, 4-8 and 10-14, as previously applied to claim 2, are objected, to because of the informalities, for reciting non-elected inventions and therefore do not set forth the invention under examination, is maintained.

***Prior Art Rejections***

12. The rejection of claims 1-2, 5, as previously applied to claim 1, 2 and 4 under 35 U.S.C. 102(b) as being anticipated by Granstrom et al (1993) is maintained for reasons of record in light of the fact that the claims still encompass derived antigen compositions. The rejection of claims 4, 6-8 has been obviated by limiting the compositions to inactivated whole cell compositions.

13. The rejection of claims 1-2, 5, under 35 U.S.C. 102(b) as being anticipated by Granstrom et al (1993) as evidenced by US Pat. 5,554,371 (detailed description paragraph 31) is traversed on the grounds that "the reference does not describe the same entity as Applicants' immunogenically active component" and asserts that inactivation by formalin is not taught by Granstrom et al.

14. It is the position of the examiner that the claimed invention may be any and all merozoite derived antigens obtained Sarcocystis neurona cells and the cells may be inactivated by chemical means. Granstrom et al inactivated the cells by chemical means



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(see Instant Specification, page 9, last paragraph), specifically solubilization (p88, table 1, p89).

15. Independent claim 1 recites the phrases: “inactivated *Sarcocystis neurona* merozoite cells” and “inactivated *Sarcocystis neurona* merozoite antibody inducing antigen derived from *Sarcocystis neurona* cells”. No specific “entity” is recited in the claims. What is the entity Applicant is referring that is not described in Granstrom? If Applicant is referring to the Deposited strain, while the claims encompass this strain as a source of antigen, the claims are not limited to this source in light of the instant Specification at page 7, lines 8-11 defining any strain of *Sarcocystis neurona* as a source of inactivated cells and derived antigen and suggests a plurality of *Sarcocystis neurona* type strains at page 7, lines 28-31 of the Instant Specification. Amendment of the claims to be limited to the Deposited strain as the only source of antigen for the inactivated whole cells could obviate this prior art rejection.

Additionally, it is the position of the examiner that what is now claimed is not limited to formalin-inactivated antigen. None of the claimed compositions comprise formalin. The antigens of Granstrom were immunologically reactive with antibodies to *Sarcocystis neurona*, and therefore were antibody inducing antigens when cell associated. Applicant's traversal is not commensurate in scope with the instantly claimed invention.

A recited intended use of the claimed compositions does not structurally and functionally distinguish over the compositions of the applied prior art as

the source of the antigen is identical: *Sarcocystis neurona*

the antigen was immunoreactive with antibodies

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the composition comprised inactivated antigen from at least  $1 \times 10^4$  cells (p88,col.1) as well as derived antigens from the inactivated antigen cells.

By comparable data, the compositions of Granstrom et al is the same or equivalent immunogenically active component now claimed. No side-by-side comparison has been submitted to show that the antigen of Granstrom et al does not meet the claimed functional characteristics of being inactivated, antibody inducing and immunogenically active. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

Inherently the reference anticipates the now claimed invention. *Atlas Powder Co. V IRECA*, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art functioning, does not render the old composition patentably new to the discoverer. The Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

16. The rejection of claims 1-2, 4-7 under 35 U.S.C. 102(b) as being anticipated by Liang et al (1998) is traversed on the grounds that:

17. "Liang et al do not describe the same immunologically active component as Applicant's claim in the present Application because the reference does not show any isolated immunogenically active antigen that would be useful for preventing EPM disease.

18. It is the position of the examiner that the recited intended use of the instantly claimed compositions does not define over the applied prior art. Liang et al disclose the instantly claimed invention directed to compositions of inactivated *Sarcocystis neurona* whole cells, wherein the cells ( $8 \times 10^7$  merozoites) of Liang et al were inactivated by heating in a boiling bath (see page 1834, col. 2, paragraph 6) and were also inactivated

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by treatment with lyses buffer (pH 7.6) (see page 1835, col. 1, paragraph 3), or by extraction by trypsin digestion (see page 1835, col. 2, paragraph 2) were inactivated cells by. In response to applicant's argument that for use as a vaccine, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

19. The isolated and purified antigens derived from the inactivated cells evidenced relative molecular weights of 30, 16, 14 and 11 kDa (see page 1835, col. 2, paragraph 4 and page 1836, Figure 3) were visualized and found to immunoreact with neutralizing antibodies (see Figure 2, and col. 1, paragraph 1, page 1836). The rejection is maintained for reasons of record.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

Inherently the reference anticipates the now claimed invention. *Atlas Powder Co. v IRECA*, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

20. The rejection of claims 1-2, and 5 under 35 U.S.C. 102(e) as being anticipated by *Mansfield et al* (US Pat. 6,489,148, effective filing date September 18, 1998) is traversed

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on the grounds that: heat denatured cells are not equivalent to the immunogenic compositions or vaccine of the present invention.

21. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

22. In response to applicant's arguments, the recitation "for preventing or ameliorating" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

23. Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

Mansfield et al disclose compositions that comprise immunogenically active components of inactivated *Sarcocystis neurona* merozoite (see col. 6, line 8) derived antigens of 30 and 16 kDa (see claims 2 and 11, col. 9 and 10), which are referred to as "immunodominant proteins (see col. 7, line 63)".

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The active components were combined in a gel and contacted with buffered saline containing tween and tris (see col. 6, lines 8-19 and lines 63-67), which serve as carriers for the derived antigens. Mansfield et al anticipates the instantly claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

Inherently the reference anticipates the now claimed invention. *Atlas Powder Co. v. IRECA*, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art."

24. The rejection of claims 1-2, 4-8, 10-14 under 35 U.S.C. 102(b) as being anticipated by Dubey et al (1999) is traversed on the grounds that:

a. Dubey et al does not use formalin to inactivate whole cells of *S. neurona*.

25. It is the position of the examiner that none of the claims require the presence of formalin, but are directed to compositions of inactivated whole cells or inactivated derived protein antigens derived from *S. neurona* whole cells that are immunoreactive and immunogenically active.

26. Applicant asserts that the Dubey et al does not make a killed vaccine.

27. It is the position of the examiner that the term "vaccine" is a type of recited intended use of a composition claim. In response to applicant's arguments, the recitation "for preventing or ameliorating" or "vaccine" has not been given patentable weight

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because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

28. In response to applicant's argument that "vaccine" or "for preventing or ameliorating", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

29. Dubey et al is asserted to not administer inactivated *S. neurona* cells on the third inoculation because "there is no indication that the third inoculation contained inactivated *S. neurona* cells"

30. It is the position of the examiner that Dubey et al obtained  $1.7 \times 10^7$  merozoite *Sarcocystis neurona* cells (see "filtered organisms" (page 501, col. 1, paragraph 4, title "Sarcocystis neurona isolate") from in vitro culture of *Sarcocystis neurona* strain SN6 (title), which is a type strain listed as a source of antigen in Applicant's Specification at page 7, last line. The in vitro culture method utilized 17-d bovine turbinate cell culture for increasing the number of *Sarcocystis neurona* SN6 cells; the method of culturing being incorporated by reference to Lindsay et al 1999 (second full reference to Lindsay, page 506, col. 1). Once Dubey et al produced a composition of  $1.7 \times 10^7$  *Sarcocystis*

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neurona cells, the cells were frozen with a combination of dry ice and 95% ethanol at -70 degrees celcius. Freezing a cell to - 70 degrees celcius would inactivate the cell from carrying on cell division, and general metabolic activities that are temperature dependent. 95% ethanol is known dehydrate compositions and to have disinfectant properties. The Center for Disease Control website defines a solution of 95% ethanol as a solution for reducing the number of viable microorganisms and is considered to be a waterless antiseptic agent not requiring the use of exogenous water.

31. Therefore, the reference discloses an inactivated composition of merozoite (see page 501, paragraph 4, middle of paragraph "merozoites of a recent isolate of S.neurona") Sarcocystis neurona whole cells, the inactivation being accomplished with chemical treatment with ethanol, dry ice and a freezing temperature. This composition was combined with an adjuvant that contained a surfactant and oil. While the word inactivated is not recited in the reference, the composition inherently comprised inactivated cells based upon the chemical nature (ethanol and dry ice) of the inactivating agents and the temperature at which the process was carried out (- 70 degrees Celcius). The rejection is maintained for reasons of record and responses set forth above.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

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true when it is not a property but an ingredient which is inherently contained in the prior art.

*Conclusion*

32. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


33. WO 97/29120; GB2310135; GB 2310212 and US006344337B1 are cited to show Sarcocystis antigen compositions.

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp  
January 30, 2006

  
**LYNETTE R. F. SMITH**  
**SUPERVISORY PATENT EXAMINER**  
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